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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE CONFIRMATION NO. LUD-5531.1 DIV 09/782,745 02/13/2001 Pierre van der Bruggen 7125

24972 7590 05/01/2002 FULBRIGHT & JAWORSKI, LLP

666 FIFTH AVE NEW YORK, NY 10103-3198

**EXAMINER** DIBRINO, MARIANNE NMN

ART UNIT PAPER NUMBER 1644

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/782,745

Applicantion

\_\_\_\_

Van Der Bruggen et al.

Examiner

Marianne DiBrino

Art Unit **1644** 



	- Th MAILING DATE of this communication appears	s on the cover she t with the corres		
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM  THE MAILING DATE OF THIS COMMUNICATION.				
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> </ul>				
<ul> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any</li> </ul>				
ear Status	ned patent term adjustment. See 37 CFR 1.704(b).			
	Responsive to communication(s) filed on <u>May 8, 20</u>	001		
2a) □	This action is <b>FINAL</b> . 2b) ☒ This acti	on is non-final.		
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle35 C.D. 11; 453 O.G. 213.			
Dispos	ition of Claims			
4) 💢	Claim(s) <u>32-40</u>		is/are pending in the applica	
4	la) Of the above, claim(s)		is/are withdrawn from considera	
5) 🗌	Claim(s)		is/are allowed.	
6) 🗌	Claim(s)		is/are rejected.	
7) 🗌	Claim(s)		is/are objected to.	
8) 💢	Claims <u>32-40</u>	are subject to	restriction and/or election requirem	
Applica	ation Papers			
	The specification is objected to by the Examiner.			
10) 🗌	The drawing(s) filed on is/a	re objected to by the Examiner.		
11) 🗌	The proposed drawing correction filed on	is: a approved	b)⊡disapproved.	
12) 🗌	The oath or declaration is objected to by the Examine	sr.		
Priority under 35 U.S.C. § 119 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) ☐ All b) ☐ Some* c) ☐None of:				
1.  Certified copies of the priority documents have been received.				
2	2.   Certified copies of the priority documents have been received in Application No			
<ol> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>*See the attached detailed Office action for a list of the certified copies not received.</li> </ol>				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).				
Attachment(s)				
	ice of References Cited (PTO-892)	18) Interview Summary (PTO-413) Paper No	o(s).	
	ice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Patent Application (PT		
17) 🔲 Info	ormation Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:		

## **DETAILED ACTION**

- 1. Applicant's amendment filed 5/8/01 is acknowledged and has been entered.
- 2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 32-40, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor antigen rejection precursor, the amino acid sequence of which is set forth in SEQ ID NO: 27, an expression vector comprising said isolated nucleic acid molecule operably linked to a promotor, an isolated cell comprising the said nucleic acid molecule or the said expression vector, and a kit useful in transforming a cell, classified in Class 536, subclass 23.5, Class 435, subclasses 252.3, 320.1 and 975.
- II.Claims 32-40, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor antigen rejection precursor, the amino acid sequence of which is set forth in SEQ ID NO: 28, an expression vector comprising said isolated nucleic acid molecule operably linked to a promotor, an isolated cell comprising the said nucleic acid molecule or the said expression vector, and a kit useful in transforming a cell, classified in Class 536, subclass 23.5, Class 435, subclasses 252.3, 320.1 and 975.
- III. Claims 32-40, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor antigen rejection precursor, the amino acid sequence of which is set forth in SEQ ID NO: 29, an expression vector comprising said isolated nucleic acid molecule operably linked to a promotor, an isolated cell comprising the said nucleic acid molecule or the said expression vector, and a kit useful in transforming a cell, classified in Class 536, subclass 23.5, Class 435, subclasses 252.3, 320.1 and 975.
- IV. Claims 32-40, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor antigen rejection precursor, the amino acid sequence of which is set forth in SEQ ID NO: 30, an expression vector comprising said isolated nucleic acid molecule operably linked to a promotor, an isolated cell comprising the said nucleic acid molecule or the said expression vector, and a kit useful in transforming a cell, classified in Class 536, subclass 23.5, Class 435, subclasses 252.3, 320.1 and 975.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino, Ph.D.

Patent Examiner Group 1640

Technology Center 1600

April 26, 2002

CHRISTINA CHAN

SUPERVISORY PATENT EXAMINER

**TECHNOLOGY CENTER 1600** 

Serial No. 09/782,745 Art Unit 1644

- V. Claims 32-40, drawn to an isolated nucleic acid molecule which encodes a GAGE tumor antigen rejection precursor, the amino acid sequence of which is set forth in SEQ ID NO: 31, an expression vector comprising said isolated nucleic acid molecule operably linked to a promotor, an isolated cell comprising the said nucleic acid molecule or the said expression vector, and a kit useful in transforming a cell, classified in Class 536, subclass 23.5, Class 435, subclasses 252.3, 320.1 and 975.
- 4. Inventions I, II, III, IV and V are different products.

The isolated nucleic acid molecules of Groups I-V are distinct because their structures are different and they may derive from different genes, which requires non-coextensive searches.

Therefore they are patentably distinct.

- 5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-V is not required for any other group from Groups I-V and Groups I-V have acquired a separate status in the art as shown by their divergent subject matter and the searches are not co-extensive, restriction for examination purposes as indicated is proper.
- 6. It is requested that Applicant disclose which one of SEQ ID NO: 27-31 are encoded by which one of SEQ ID NO: 14-18. For example, is SEQ ID NO: 27 encoded for by SEQ ID NO: 14?
- 7. This application contains claims directed to the following patentably distinct species of the claimed invention of Groups I-V: wherein the HLA molecule is:
  - A) HLA-Cw6 or
  - B) HLA-A29

These species are distinct because their structures and modes of action are different and they bind to peptides with different binding motifs and elicit differently restricted immune responses.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.